

Appl. No. : 10/742,156
Filed : December 19, 2003

REMARKS

The claim amendments and remarks herein are responsive to the Office Action dated January 13, 2006. Applicant has amended Claim 1 and has added Claims 10-17.

Claim Rejections

Rejection Under 35 U.S.C. § 102 Or § 103

The Examiner rejected Claims 1-9 under 35 U.S.C. § 102(b), or in the alternative under 103(a), over US Patent No. 5,342,394 to Matsuno.

Applicant's embodiments, as recited in the pending claims of the instant application, are designed to function in an environment that is entirely different than the environment disclosed in Matsuno. For example, Applicant's embodiments are design to work in an environment encumbered by bony or spinal tissue (such as the intervertebral disc). By contrast, Matsuno is designed to operate in the venous system.

Matsuno merely discloses passing a bent tipped cannulated device through a vein and then advancing the device within the vein. An inner cannulated member is then laterally extruded into the opening of a vein branch. Thereafter, a balloon-like blocking means is extruded from the inner cannulated member and expanded to block the branch. *See Matsuno at 1:54-65.*

Applicant has amended Claim 1 to recite: "locating an opening in the outer layer, wherein said outer layer comprises bony or spinal tissue." To anticipate a claim, the reference *must teach every element of the claim*. According to the M.P.E.P. § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" (quoting *Verleagal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). M.P.E.P. § 2131 also expressly provides that "[t]he identical invention must be shown in as complete detail as is contained in the ... claim" (quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1235, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Here, nowhere does Matsuno teach or suggest the manipulation of tissue encumbered by bony or spinal tissue. Moreover, Matsuno does not disclose a device capable of being advanced and retracted through a curved slot. Thus, Matsuno cannot anticipate Applicant's claims

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Any argument that Applicant's claims would be obvious over Matsuno would also fail. As emphasized in MPEP § 2141:

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and **must suggest the desirability and thus the obviousness of making the combination;**
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (D) **Reasonable expectation of success** is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Here, there is no suggestion in Matsuno whatsoever that the Matsuno device/method can be used to navigate bony or spinal environments. Moreover, there is no disclosure that one would have a reasonable expectation of using Matsuno's device/method in bony or spinal environments. As explained in Applicant's specification, delicate and precise work within, for example, the disc environment is very different than working in, for example, a venous system. Applicant explains that certain devices:

can exit the annulus and cause considerable damage to the surrounding tissues and spinal cord. Also, the flexible probe tips on some instruments which permit access to remote locations within the disc can only do so by sacrificing direct control because the devices are passively guided or blindly "snaked" within the disc. Accordingly, delicate and precise work within a disc is not possible with such instruments.

Applicant's specification at ¶ 8. Applicant's specification further explains:

Among other disadvantages, the devices and methods of the prior art are typically invasive and destructive to surrounding tissue, frequently causing disc infection and nerve root injury. Moreover, such devices are unable to precisely manipulate disc material along the posterior annulus in a minimally invasive manner. Accordingly, there is a need for an intervertebral disc diagnostic and manipulation device which is capable of performing delicate and precise work within a disc, especially along the posterior annulus and between annular lamella.

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Id. at ¶ 8. Thus, there can be no reasonable dispute that a method for manipulating tissue in an environment encumbered by bony or spinal tissue is novel and non-obvious over a device/method for accessing a vein.

Accordingly, Claims 1 and 9 are patentable over the cited art. Claims 2-8 are also patentable because they recite independently patentable features and depend from an allowable base claim (Claim 1).

New Claims

Applicant has added New Claims 10-17. No new matter has been added by these claims. Non-limiting support for New Claims 10-17 can be found, inter alia, in the specification as follows:

Claim 10. The method of Claim 1, further comprising inserting a prosthetic device beyond said opening in the outer layer.	E.g., ¶ 00:17
Claim 11. The method of Claim 1, further comprising ablating a target tissue.	E.g., ¶ 00:33
Claim 12. The method of Claim 1, wherein said bony or spinal tissue comprises intervertebral disc tissue.	E.g., ¶ 00:0
Claim 13. The method of Claim 1, wherein said bony or spinal tissue comprises anulus fibrosis.	E.g., ¶ 00:0
Claim 14. The method of Claim 1, further comprising forcibly parting at least a portion of the tissue without cutting it.	E.g., ¶ 00:1
Claim 15. The method of Claim 1, further comprising forcibly cutting at least a portion of the tissue.	E.g., ¶ 00:1
Claim 16. The method of Claim 1, further comprising aspirating fluid using one or more lumens located within said cannula.	E.g., ¶ 00:4
Claim 17. The method of Claim 1, further comprising delivering material using one or more lumens located within said cannula.	E.g., ¶ 00:4

New Claims 10-17 are patentable over the cited art because they depend from an allowable base claim (Claim 1), and additionally because they recite independently patentable features.

In view of the above amendments and remarks, Applicant respectfully asserts that Claims 1-17 are patentable over the cited art, and requests that the Examiner allow these claims.

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Applicant respectfully asserts that the present application is fully in condition for allowance. *If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below.*

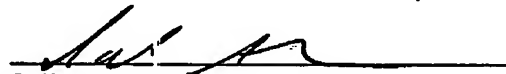
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: July 11, 2006

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